United States District Court
District of Massachusetts

SECURITIES AND EXCHANGE COMMISSION,	)	
Plaintiff	)	
v.	)	**Civil Action No. 16-10607-NMG**
DAVID JOHNSTON	)	
Defendant.	)	

MEMORANDUM & ORDER

Gorton, J.

This case arises out of the development of a cancer drug by AVEO Pharmaceuticals, Inc. ("AVEO"). The Securities and Exchange Commission ("the SEC") alleges that AVEO, its chief executive officer Tuan Ha-Ngoc ("Ha-Ngoc"), chief financial officer David Johnston ("Johnston" or "defendant") and its chief medical officer William Slichenmyer ("Slichenmyer") made materially misleading statements to investors about communications with the Food and Drug Administration ("the FDA") during their bid for approval of their flagship drug candidate, tivozanib ("Tivo").[1] The SEC contends that AVEO, through Johnston, concealed from investors the critical fact that the

[1] The SEC and AVEO entered into a consent judgment in March, 2016 and the SEC separately reached settlements with defendants Ha-Ngoc and Slichenmyer. Johnston is the only remaining defendant.

FDA recommended that AVEO conduct a second clinical trial in order to secure approval for Tivo.

Pending before the Court is Johnston's motion for summary judgment (Docket No. 86). For the reasons that follow, that motion will be denied.

I. Background

A. FDA Approval Process

To obtain FDA approval to market and sell a drug in the United States, a pharmaceutical company must demonstrate the drug's safety and efficacy through human clinical trials conducted in three phases. After the third phase of the trial, a company can seek approval from the FDA by submitting a New Drug Application ("NDA") which, if accepted, leads either to a substantive review or a Refusal to File ("RTF") letter from the FDA. If the NDA is accepted for filing, the FDA sends a letter ("the Day 74 Letter") which confirms certain logistics and identifies any preliminary deficiencies in the application. Upon receipt of the Day 74 Letter, an applicant has the opportunity to respond to any concerns by amending the NDA.

During the review process for cancer therapeutics, the FDA may convene an advisory panel of outside experts called an Oncologic Drugs Advisory Committee ("ODAC"). The ODAC provides additional review of the safety and efficacy of proposed drugs by holding non-binding votes on questions posed by the FDA.

Before ODAC meetings, the FDA and the pharmaceutical company release the pre-meeting summaries for those meetings. The FDA makes the final determination on the NDA as to whether to approve the drug unconditionally, approve the drug with certain conditions or deny approval.

B. Tivo

AVEO is a publicly-traded biopharmaceutical company that develops oncology medicines, incorporated in Delaware with its headquarters in Boston, Massachusetts. In 2012 and 2013, Johnston was the chief financial officer ("CFO") of AVEO and, in that capacity, he was a member of AVEO's Executive Committee, responsible for the company's strategic decisions, and its Disclosure Committee.

On AVEO's Form 10-K for fiscal years 2011 and 2012, the company reported that it was developing a cancer therapy, Tivo, which would be indicated for the treatment of renal cell cancer. AVEO had begun sponsoring a Phase 3 drug trial ("TIVO-1") in 2009 to measure Tivo's efficacy and safety against a control group that received sorafenib, an approved therapy for renal cell cancer.

In May, 2012, representatives from AVEO and its business partner Astellas Pharma, Inc. ("Astellas") met with the FDA in advance of submitting the NDA for Tivo ("the pre-NDA meeting"). Prior to the meeting, AVEO sent the FDA data derived from TIVO-

1, AVEO's only Phase III trial. The data indicated that Tivo met its primary endpoint but that the secondary endpoint, measuring overall survival (the period of time a patient lives while taking the drug), trended in a negative direction. The minutes of the pre-NDA meeting indicate that the FDA voiced doubts about the drug's safety and efficacy because of the TIVO-1 secondary endpoint results. The minutes note that

> [t]he Agency expressed concern about the adverse trend in overall survival. Further discussion of these findings will be required at the time of filing and if the application is filed they will be a review issue that could affect approvability. FDA recommended that the sponsor conduct a second adequately powered randomized trial in a population comparable to that in the US.

One member of the FDA staff suggested that the trend in the secondary endpoint could cause the FDA to issue an RTF letter.

After the pre-NDA meeting, Johnston attended an AVEO Executive Committee meeting and a board meeting to discuss the results of the pre-NDA meeting and budgeting for a second Phase III trial of Tivo ("TIVO-2"). Although AVEO sought a meeting with the FDA to discuss TIVO-2's design and timing, the company withdrew that request when the FDA expressed "significant concerns regarding the trial design described in [AVEO's] meeting package". Rather than pursuing the second trial, AVEO decided to submit the NDA, relying on the results of TIVO-1. In August, 2012, AVEO provided a regulatory update in a public press release, stating that

> [t]he FDA has expressed concern regarding the OS trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing.

Following the issuance of that press release, AVEO prepared a script for a conversation with investors and analysts in which Johnston participated. During that conversation, Dr. Slichenmyer stated that he could not speculate as to what additional action the FDA might require. AVEO filed its quarterly Form 10-Q shortly thereafter which Johnston signed. That form did not mention any recommendation of the FDA for a second randomized trial. AVEO submitted another 10-Q in November, 2012 with identical disclosure language.

In November, 2012, the FDA accepted and filed the NDA which initiated the process of substantive review. The FDA sent a Day 74 letter in which it stated that the TIVO-1 results remained a "significant safety concern" for the agency that it intended to discuss at a May, 2013 meeting with the ODAC convened to review Tivo.

In January, 2013, AVEO filed an 8-K with the SEC. That 8-K did not address the FDA's recommendation that the company undertake a second trial or mention AVEO's plans to set up TIVO-2. The next day, AVEO filed a prospectus in anticipation of offering 6,667,000 shares of common stock, priced at $7.50 per share. AVEO raised approximately $53.8 million in connection with its stock offering.

In advance of the May, 2013 meeting of the ODAC, the FDA released a public briefing book concerning Tivo in which it disclosed that it had previously recommended that AVEO conduct a second trial of TIVO. After the release of the briefing book, AVEO's stock price declined by approximately 30%. On May 2, 2013, the ODAC voted 13 to 1 against approving Tivo and the following month the FDA decided not to approve the drug.

C. Procedural History

The SEC filed the instant action in March, 2016, at which time it entered into a consent decree with AVEO. Later that year, the SEC filed its first amended complaint, alleging violations of Section 10(b) of the Securities Exchange Act of 1934 ("the Exchange Act") and Rules 10b-5 and 13a-14 thereunder and violation of Section 17(a) of the Securities Act of 1933 ("the Securities Act"). In 2017 and early 2018, the SEC entered into settlement agreements with defendants Ha-Ngoc and Slichenmyer. In January, 2018, Johnston moved for summary judgment on all claims against him. That motion is the subject of this memorandum.

III. Motions for Summary Judgment

A. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d

816, 822 (1st Cir. 1991). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

B. Application

1. Duty to Disclose

Johnston first contends that the information omitted by AVEO was not material because any potential disclosure about the FDA's recommendation that AVEO conduct a second trial was not obligatory. Because the FDA's recommendation was not a directive, he suggests it merely created a possibility that an adverse event affecting AVEO could occur at some later point. He submits that the FDA's recommendation was part of the regulatory back-and-forth between the agency and the company and that it contemplated a risk that was too uncertain to merit disclosure. The drug approval process is inherently risky and the FDA's statements were innately provisional. He notes that a company has no duty to disclose normal risks and ongoing discussions with the agency.

The SEC rejoins that the recommendation was material and, in any event, the determination of materiality should be left to the jury. The SEC emphasizes an Executive Committee slide deck, reviewed by Johnston, which noted that failure to conduct a second trial would lead to a high risk of non-approval. It proffers evidence demonstrating the importance of the recommendation to investors, namely the steep reduction in stock price after the FDA disclosed its recommendation. The SEC also submits that the recommendation was important to AVEO

internally, prompting the budgeting and design of TIVO-2 and internal discussions at board meetings.

SEC Rule 10b-5 implements the Exchange Act by making it unlawful to

> make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading.

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (citing 17 C.F.R. § 240.10b-5(b)). To prevail on a 10b-5 claim, a plaintiff must establish, in relevant part, that the defendant made (1) a material misrepresentation or omission with (2) scienter, or a wrongful state of mind (3) in connection with the purchase or sale of a security. Deka Int'l v. Genzyme Corp., 754 F.3d 31, 40 (1st Cir. 2014).

To establish that the defendant made a material omission, a plaintiff must show that defendant had a duty to disclose the omitted information. In re Biogen Sec. Litig., 179 F.R.D. 25, 34 (D. Mass. 1997). Although it is well established that a company need not disclose every fact that an investor may find "interesting or desirable", information is considered material if it would

> alter the total mix of facts available to the investor and if there is a substantial likelihood that a reasonable shareholder would consider it important to the investment decision.

Milton v. Van Dorn Co., 961 F.2d 965, 969 (1st Cir. 1992) (quoting Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)). Any voluntary disclosure of information that a reasonable investor would consider material must be "complete and accurate" and a company must disclose facts that are necessary so that "what was revealed would not be so incomplete as to mislead". Tutor Perini Corp. v. Banc of Am. Sec. LLC, 842 F.3d 71, 88 (1st Cir. 2016) (internal citation omitted).

A showing of materiality on summary judgment depends on whether a plaintiff could persuade a reasonable juror to find that a reasonable investor would view the omission as altering the total mix of facts available to the investor. In re Biogen, 179 F.R.D. at 35. The materiality of an omission is a question generally left to the jury. Lucia v. Prospect Street High Income Portfolio, Inc., 36 F.3d 170 (1st Cir. 1994) (noting that "whether an omission or misleading statement is material is normally a jury question and should not be taken from it unless the court has engaged in meticulous and well articulated analysis of each item of withheld or misrepresented information") (internal citation omitted).

When the record is viewed in the light most favorable to the SEC, a reasonable jury could conclude that the FDA's recommendation that AVEO undertake a second clinical trial significantly altered the total mix of information then

available in the marketplace such that it was material. See In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012). Here, the FDA's recommendation created a possibility that an event affecting AVEO, a decision not to approve Tivo, could have been material to a reasonable investor. Where information creates a possibility that an event will later occur, the materiality of the information depends on a balancing of the indicated probability that an event will occur and the "anticipated magnitude of the event in light of the totality of the company activity". Id. (citing SEC v. Tex. Gulf Sulphur Co., 401 F.2d 833, 849 (2d Cir. 1968) (en banc)).

The SEC presents evidence suggesting that the stakes for approval of Tivo were very high for AVEO because Tivo was its only drug candidate. In its 2011 and 2012 10-K, AVEO reported that the company was "dependent on the success of its lead drug candidate, tivozanib". Accordingly, considering the potential magnitude of non-approval in light of AVEO's outlook and activity, there is a substantial likelihood that a reasonable investor would have considered information about the FDA's recommendation important to the investment decision. Id. (citing Basic, 485 U.S. at 231-32).

Johnston contends that the recommendation merely constituted interim regulatory feedback that was too indefinite to merit disclosure. The First Circuit Court of Appeals ("the

First Circuit") has made clear that a company need not disclose all regulatory dialogue with an agency because it may be irresponsible to issue "an ominous warning about an uncertain risk" without adequate investigation into the risk. Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 244 (1st Cir. 2015) (citing In re Boston Sci., 686 F.3d at 31). In Abiomed, however, the First Circuit noted that the defendant company had explicitly warned investors that (1) the FDA may disagree with the company's assessment of the legality of its marketing and (2) an FDA enforcement action could result in a reduced demand for its products. Id. at 243. Analagous disclosures were not made by Johnston or AVEO.

The general public disclosures made by AVEO and Johnston, including the August, 2012 press release and regulatory update, August, 2012 10-Q, Johnston's presentations at two September conferences and the November, 2012 10-Q contain no explicit warnings as was the case in Abiomed. Johnston repeatedly emphasizes that the company made the results of TIVO-1 known and that those negative results could impede the approval process of Tivo. A reasonable jury could find that the disclosures made by Johnston and AVEO would mislead rather than adequately inform prospective investors because of the omission of the recommendation for a second trial. See In re Biogen, 179 F.R.D. at 35 (citing Lucia, 36 F.3d at 175) ("[T]he disclosure required

by securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers.").

Furthermore, Johnston's emphasis on the uncertainty of the risk of non-approval is undercut by evidence proffered by the SEC of Johnston and AVEO's internal assessment of the risk. AVEO and Johnston actively pursued budgeting and designing TIVO-2, leading to the reasonable inference that there was concern about the likelihood of approval without a second clinical trial. Johnston also participated in the review of a slide deck prepared by AVEO's chief medical officer summarizing the pre-NDA meeting which highlighted the "high risk" of non-approval or an RTF letter if AVEO chose not to pursue a second clinical trial. Viewing the record in the light most favorable to plaintiff, the SEC has raised a genuine issue as to the materiality of the FDA's recommendation.

2. Scienter

Johnston also moves for summary judgment on the grounds that the SEC is unable to prove that he acted with the requisite state of mind. First, Johnston asserts that any inference of scienter is undermined by the absence of evidence that there was any duty to disclose. Johnston then suggests that the uncertainty of the negative regulatory outcome precludes an inference of scienter here. He maintains that his understanding

of the risk was also attenuated because he did not attend the pre-NDA meeting and his conception of the risk came instead from the advice of two regulatory experts, an attorney and a former FDA official.

The SEC rejects Johnston's version of the facts, contending that the record demonstrates a genuine dispute about whether Johnston knew or recklessly disregarded the fact that Tivo faced a high-risk of non-approval without a second trial. The SEC contends that a defendant's state of mind is generally a jury question. It denies that Johnston's reliance on other regulatory experts negates a finding of scienter because AVEO has not waived the privilege with respect to its lawyers' advice. Finally, the SEC submits that Johnston's limited disclosures do not demonstrate that he acted in good faith to disclose the full measure of the FDA's concerns.

To prevail on a Rule 10b-5 claim, a plaintiff must prove that the defendant acted with scienter, "a mental state embracing intent to deceive, manipulate, or defraud". Tellabs, 551 U.S. at 319 (citing Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). The First Circuit has held that proof of a "high degree of recklessness" is also sufficient. Abiomed, 778 F.3d at 243. In the context of demonstrating a defendant's scienter, recklessness does not include "ordinary negligence, but is closer to being a lesser form of intent". Id. (citing

Greebel v. FTP Software, Inc., 194 F.3d 185, 188 (1st Cir. 1999)). Although the issue of scienter is generally a jury question, summary judgment

> may be appropriate if the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation.

SEC v. Ficken, 546 F.3d 45 (1st Cir. 2008) (internal citation omitted) (affirming district court's order granting summary judgment for plaintiff SEC finding that there was no genuine dispute that defendant had the requisite scienter).

The SEC proffers Johnston's deposition testimony in which he describes the work of AVEO's communications team (which Johnston managed) to prepare a script reflecting "hot button areas" in preparation for a call with analysts. That script notes that, if asked about the need for additional clinical studies, the appropriate response would be that "[a]t this time, the Agency has not required an additional study for approval". There is an internal note, however, that states "IF PUSHED . . . details on discussions with FDA". The First Circuit has stated that "divergence between internal reports and external statements on the same subject" can constitute evidence relevant to a showing of scienter. Greebel, 194 F.3d at 196.

Johnston places heavy emphasis on the "Risk Factors" included in AVEO's formal SEC filings, contending that the disclosures about the adverse TIVO-1 data sought to provide

investors with adequate warnings. Johnston is correct that the provision of warnings to investors can "erode[] inferences of scienter". Kader v. Sarepta Therapeutics, Inc., No. 17-1139, 2018 WL 1616954, at *7 (1st Cir. April 4, 2018) (citing (Abiomed, 778 F.3d at 244). In Kader, however, the First Circuit noted that the communication that allegedly omitted material information in fact reiterated a previous disclosure that made clear to investors that the FDA was looking for further review. Id. The Court found that the subject communication did not omit new material information and stated that scienter could not be inferred from the company's decision not to "elaborate more fully". Id. In the case at hand, however, there was no previous disclosure that described the pre-NDA meeting.

While Johnston and AVEO did provide warnings about the TIVO-1 results, the SEC presents evidence that investors were not informed about the FDA's recommendation that a second clinical trial would likely be necessary. A reasonable factfinder could find that the disclosures made were insufficient to "weaken the inference of scienter", City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 760 (1st Cir. 2011), and that the public-facing statements made by Johnston and AVEO diverged significantly from internal discussions such that a jury could

infer an intent to deceive. Greebel, 194 F.3d at 196. Accordingly, Johnston's motion for summary judgment, with respect to scienter, will be denied.

3. Rule 13a-14 Claim

Johnston also suggests that he is entitled to summary judgment on the SEC's Rule 13a-14 claim because that rule does not create a separate cause of action. He contends that, even if the Rule creates a separate cause of action, it merely creates liability for false statements and alleged omissions are not actionable where the defendant had no duty to disclose. The SEC maintains that defendant has such a duty and that, therefore, the relevant Commission filings contained materially misleading statements.

Rule 13a-14 mandates that, for each report filed under Section 13(a) of the Exchange Act, each principal executive and financial officer of the issuing company must sign a certification as to the accuracy of the financial statements within the report. 17 C.F.R. § 240.13a-14 (2002). The certifying executives and officers are required to attest that the reported information

> does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading.

15 U.S.C. § 7241(a)(2). The First Circuit has not yet considered whether Rule 13a-14 provides a separate cause of action. One circuit court of appeals has addressed the question and has found that it creates a cause of action. SEC v. Jensen, 835 F.3d 1100, 1113 (9th Cir. 2016); see also SEC v. e-Smart Tech., Inc., 31 F. Supp. 3d 69, 86 (D.D.C. 2014) (surveying cases that have allowed a claim under Rule 13a-14 based on misrepresentation to proceed).

Accordingly, this Court will allow the Rule 13a-4 claim to proceed. As explained above, viewing the record in the light most favorable to plaintiff, the SEC has raised a genuine issue of material fact as to whether Johnston failed to disclose materially misleading information with the requisite scienter and, by extension, falsely certified the relevant Commission filings. Jensen, 835 F.3d at 1113 ("It is not enough for CEOs and CFOs to sign their names to a document certifying that SEC filings include no material misstatements or omissions without a sufficient basis to believe that the certification is accurate."). Johnston's motion for summary judgment as to the SEC's Rule 13a-14 claim will be denied.

ORDER

For the foregoing reasons, Johnston's motion for summary judgment (Docket No. 86) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton_____
Nathaniel M. Gorton
United States District Judge

Dated April 19, 2018